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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,554

Applicant(s)

YOSHII, HIROTO

Examiner

Channing S Mahatan

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 22-45, 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election without traverse of Group I (claims 1-21 and 46-48; drawn to a probe design method utilizing a tree/node structure and apparatus and program therefor) in the response, filed 04 December 2003, is acknowledged.

Claims 22-45 and 49-50 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response file 04 December 2003.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-21 and 46-48.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

SCOPE OF ENABLEMENT

Claims 1-21 and 46-48 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for evaluating a probe of a partial base sequence the by the entropy calculation (page 18) for the measurement of specificity of a partial base sequence by a noted of the discrimination tree and evaluation of said entropy by the disclosed evaluation function(s) on pages 19-21, does not reasonably provide enablement for all forms of evaluating, and all functions for evaluation of a partial base sequence represented by a desired node as encompassed by the instant claims.

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Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claim 1 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. Instant claim 1 recites “the evaluation step of evaluating the suitability as a probe of a partial base sequence represented by a desired node...” and it appears the only support for such an evaluation step in the specification is found on pages 16-21 (‘Probe Evaluation Method (Step S104)’ and Figure 1. This section indicates the evaluation of a node (within the discrimination tree) as a probe is based upon the measurement of the specificity (entropy; Equation 1) of a partial base sequence specified by a node of the discrimination tree for evaluation.

“Therefore, it is necessary to measure the specificity of the a partial base sequence specified by a node of the discrimination tree.” (page 18, lines 9-12 of the Specification).

Further, the utilizing the specificity (entropy) of the “partial base sequence” the disclosure indicates the derivation of evaluation scores, which is used for the evaluation of partial base sequence, by specific evaluation functions (page 19-21; Equations 2 & 3) and requires the

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calculation of specificity (entropy). The specification does not provide further guidance, examples, or direction on how to perform other steps/methods of “evaluating a probe of a partial base sequence represented by a desired node”, as broadly encompassed by the instant claim language. Further, undue experimentation would be required by one of skill in the art at the time of the invention to derive other methodologies to evaluate the “suitability as a probe of a partial base sequence represented by a desired node”, since no other steps are disclosed and none is apparent. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It should be noted that although, the specification states:

“It is of course possible to measure the specificity of a base sequence by a method other than entropy herein explained.” (page 18, lines 21-23)

No other methods are generally stated or apparent to determine specificity and thereby utilizing it in the evaluation step to evaluate “the suitability as a probe of a partial base sequence represented by a desired node”. The specification fails to disclose a definition for specificity, other than that entropy is a measure of specificity, and one of skill in the art would not understand what is encompassed by “specificity” and thereby being able to measure it.

Claims Rejected Under 35 U.S.C. § 112nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-21 and 46-48 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “A probe designing method of designing a base sequence to be used as a probe which is hybridized with an unknown nucleic acid fragment to perform gene analysis”, however, the claim recites a final step of “determining a partial base sequence to be used as a probe on the basis of the evaluation result in the evaluation step”. There is no indication that a base sequence to be used as a probe which is hybridized with an unknown nucleic acid fragment to perform gene analysis is intended to be designed as recited in the preamble. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when the probe is designed. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim 1 and all claims dependent therefrom recites the phrase “suitability as a probe of a partial base sequence” which is vague and indefinite. The term “suitability” implies some form of criteria(s) that indicates a probe is suitably. Applicant can resolve this issue by indicating what Applicant regards a probe of a partial base sequence to be suitable. Clarification of the metes and bounds, via clearer claim language, is requested.

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Claims 1, 5, and all claims dependent therefrom recite the phrase “desired node” which is vague and indefinite. Applicant can resolve this issue by particularly pointing out what Applicants’ regard as “desired”. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 5, 7, and all claims dependent therefrom recites the limitation “near the center of a partial base sequence” which is vague and indefinite. The term near implies some degree/proximity/range that is considered “near the center”. Applicant can resolve this issue by indicating what the term near is intending limiting, for example, is “near” considered to be: 1) 1, 2, 3, etc. nucleotides; 2) a percentage; or 3) some value from the exact center of the partial base sequence. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 5 and all claims dependent therefrom recites the term “adequate as a probe” which is vague and indefinite. It is unclear the criteria(s)/value(s) that Applicant consider to establish a probe as adequate, via an evaluation function. Applicant can resolve this issue by particularly pointing out the criteria(s)/value(s) which are considered to deem a probe as adequate. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 7 and all claims dependent therefrom recites the limitation “attaches importance to a change” which is vague and indefinite. The phrase implies values/markers that denote importance, which is unclear. Applicant can resolve this issue by particularly pointing what values/markers are attached that indicated importance to a change. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 12 recites the limitation “selecting only a necessary and sufficient group completely independent in terms of information” which is vague and indefinite. It is unclear the

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criteria(s) Applicant regards as “necessary and sufficient” and what limitation “completely independent in terms of information” is to impart to the instant claim. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 15 recites the limitation “partial base sequences which react or do not react identically with each of the plurality of base sequence patterns” which is vague and indefinite. It is unclear what Applicant regards as a reacting with base sequence patterns, and thereby determining whether the partial base sequences react or do not react identically. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 16 recites the limitation “the base sequence order of partial base sequences represented by node connections is consistent with the base sequence order in the target” which is vague and indefinite. The term “consistent” implies a criteria(s)/parameter(s) that is used to evaluate whether or not the “base sequence order of partial base sequences” is consistent with the “base sequence order in the target”. Applicant can resolve this issue by particularly pointing what criteria(s)/parameter(s) determine consistency. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 46-48 recite the limitations “apparatus for realizing”/ “allowing a computer to realize” which is vague and indefinite. It is unclear the manner in which the apparatus realizes and the manner in which a program allows a computer to realize the probe designing method. Clarification of the metes and bounds, via clearer claim language, is requested.

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LACK OF ANTECEDENT BASIS

Claims 1, 3, 10, 11, 20, 21, and all claims dependent therefrom recites the limitation "evaluation result in the evaluation step" which lacks proper antecedent basis. No evaluation result is generated in the evaluation step (i.e. claim 1).

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

January 26, 2004

Examiner Initials:

CSM

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER

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